

Applicant : Alan D. Snow *et al.*
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Attorney's Docket No.: 017170-0010-999

REMARKS

Claims 28-38, 41, 55 and 56 are pending. Claims 1-27, 39, 40 and 42-54 are cancelled without prejudice or disclaimer. Applicant reserves the right to file divisional/continuation applications to the cancelled subject matter. Claim 28 is amended. Basis for the amendment can be found in the specification on page 40, line 26. No new matter is added.

**THE REJECTION OF CLAIMS 28-41 and 55-56 UNDER 35 U.S.C. §102(b),
OVER KUZNICKI *ET AL.***

Claims 28-41 and 55-56 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kuznicki *et al.* (U.S. Patent No. 5,681,569) because the cited reference allegedly discloses a composition containing green tea solids extracted from tea material. The extract contains 0.01-0.35% flavanols and catechins, wherein the catechin or a mixture of two or more catechins are catechin, epicatechin, gallic catechin, epigallocatechin gallate and epicatechin gallate, and a pharmaceutical carrier. The Office Action alleges that the green tea composition of Kuznicki *et al.* inherently contains proanthocyanidin oligomers having the instant formula I and II and/or procyanidins such as the dimers and trimers of catechin and epicatechin because catechins are allegedly known to encompass these compounds which are known to be isolated from green tea.

The Office Action alleges that the inherency of the green tea composition is supported by the Hashimoto *et al.* The Office Action urges that Hashimoto *et al.* discloses that proanthocyanidins are isolated from oolong tea. It is alleged that oolong tea is a well known green tea. The Office Action alleges that the compounds identified by Hashimoto *et al.* in the green tea compositions are the instant compounds having formula I or II.

The Office Action further alleges that Morimoto *et al.* also teaches proanthocyanidin containing compositions wherein the proanthocyanidins can be degraded to catechins and epicatechins.

Applicant notes that claims 39 and 40 are cancelled herein. The rejection is respectfully traversed with respect to pending claims 28-38, 41 and 55-56.

Disclosure of Kuznicki *et al.*

Kuznicki *et al.* discloses a liquid composition containing flavanols from green tea extract, sodium and potassium ions, carbohydrate and water. The reference also discloses a dry composition containing flavanols from green tea extract, sodium and potassium ions,

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carbohydrate (column 2, lines 12-32). The reference further discloses that the term flavanol or catechin means primarily catechin, epicatechins, and their derivatives (column 3, lines 20-21). The reference discloses that the derivatives include sugar, salts, sugar esters, and other edible physiologically available derivatives. It is disclosed in the reference that the flavanols used therein can be extracted from fruits, vegetables, green tea or other natural sources (column 4, lines 9-11).

Disclosure of Hashimoto *et al.*

Hashimoto *et al.* discloses components of oolong tea extract in 80% aqueous acetone. The reference discloses that polyphenolic constituents in the 80% aqueous acetone extract of oolong tea include flavan-3-ol, dimeric flavan-3-ols and proanthocyanidins.

Disclosure of Morimoto *et al.*

Morimoto *et al.* discloses components of *Illicium anisatum* extract in 80% aqueous acetone. The reference discloses that the 80% aqueous acetone extract of *Illicium anisatum* contains several procyanidins, including compounds of formula I and II. The reference does not disclose components of green tea extract.

Analysis

It appears that the allegations in the Office Action are based on the premise that the green tea extract inherently contains the compounds present in the oolong tea extract. It is well known in the art that oolong tea is manufactured by partial oxidation of tea leaves. Green tea, on the other hand, is manufactured by steaming or drying fresh tea leaves at elevated temperatures. In the manufacture of oolong tea the monomeric flavanols undergo oxidative polymerization leading to the formation of oligomers of the flavanols. Therefore, applicant respectfully submits that the components of the green tea composition disclosed in Kuznicki *et al.* are not the same as those of 80% aqueous acetone extract of oolong tea disclosed in Hashimoto *et al.*

Applicant has provided several references in the response dated October 14, 2004, that report the studies conducted on the components of green tea. Applicant is not aware of any reference that indicates the presence of a proanthocyanidin, selected from a group of proanthocyanidins characterized by Formula I or Formula II, and proanthocyanidins characterized by oligomeric combinations of Formula I and Formula II in green tea.

Furthermore, amended claims are directed to compositions wherein the proanthocyanidin is at

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least 70% pure and the therapeutic amount of the proanthocyanidin is selected for efficacy in treating amyloid, α -synuclein or NAC fibrillogenesis in a mammalian subject. There is no art of record that discloses such compositions.

Differences between the instant subject matter and the teachings of
Kuznicki *et al.*

Claims 28-38 and 41

Applicant notes that amended claim 28 is directed to a pharmaceutical composition containing therapeutically effective amount of a proanthocyanidin, selected from a group of proanthocyanidins characterized by Formula I or Formula II, and proanthocyanidins characterized by oligomeric combinations of Formula I and Formula II, and pharmaceutically acceptable salts of the foregoing proanthocyanidins and a pharmaceutically acceptable carrier, diluent, or excipient, wherein the proanthocyanidin is at least 70% pure and the therapeutic amount of the proanthocyanidin is selected for efficacy in treating amyloid, α -synuclein or NAC fibrillogenesis in a mammalian subject.

Kuznicki *et al.* describes compositions containing flavanols in green tea extract and further discloses that the term flavanol or catechin means primarily catechin, epicatechins, and their derivatives. Kuznicki *et al.* does not disclose that the flavanols or catechins therein encompass a proanthocyanidin, selected from a group of proanthocyanidins as described in the instant claim.

As discussed above, green tea has different chemical constitution than oolong tea. There is no suggestion in Hashimoto *et al.* that the components of an oolong tea extract described therein correspond to the components of a green tea extract. Based on various references discussed previously in applicant's response dated October 14, 2004, and further based on the disclosure of Kuznicki *et al.*, the compositions disclosed in Kuznicki *et al.* do not contain at least 70% pure proanthocyanidin selected as described in the instant claims. Further, there is no basis in the teachings of Hashimoto *et al.* to conclude that the composition containing green tea extract, disclosed by Kuznicki *et al.*, inherently contains at least 70% pure proanthocyanidins of the instantly claimed compositions because Hashimoto *et al.* discloses components of oolong tea. As discussed above, the components of oolong tea differ from the components in green tea extract.

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Applicant respectfully submits that the reference must describe the invention as claimed sufficiently to have placed a person of ordinary skill in the art in possession of the invention. An inherent property has to flow naturally from what is taught in a reference. *In re Oelrich*, 666 F.2d 573, 581, 212 USPQ 325, 326 (CCPA 1981). In the instant case, the cited reference by Kuznicki *et al.* discloses compositions containing green tea extract. Neither Kuznicki *et al.* nor any other reference of record discloses that green tea extract contain the proanthocyanidins as described in the instant claims.

Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, Kuznicki *et al.* does not anticipate a composition containing at least 70% pure proanthocyanidin as claimed in claim 28. Because claims 29-38 and 41 depend from claim 28, Kuznicki *et al.* does not anticipate any of the claims dependent on claim 28. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

Claim 55-56

Claim 55 is directed to a pharmaceutical composition containing therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins selected from a group of proanthocyanidins characterized by Formula I or Formula II, and proanthocyanidins characterized by oligomeric combinations thereof, and pharmaceutically acceptable salts of the foregoing proanthocyanidins.

Applicant respectfully submits that the cited reference does not disclose, either literally or inherently, a pharmaceutical composition containing therapeutically effective amount of proanthocyanidins selected as described in claim 55. Further, the reference does not disclose a pharmaceutical composition containing therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins selected as described above.

The Office Action alleges that the disclosed compositions contain catechins extracted from green tea and their percentage purity is known to significantly exceed a proportion percentage of the catechin present in a plant. As discussed above, the compositions containing green extract disclosed in the reference do not contain the proanthocyanidins of the instant claim. Therefore, the reference can not disclose a pharmaceutical composition containing therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins selected as described in the claim.

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Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, Kuznicki *et al.* does not anticipate a composition containing therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins as claimed in claim 55. Because claim 56 depends from claim 55, Kuznicki *et al.* does not anticipate claim 56. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

Rebuttal to Examiner's Arguments

Proanthocyanidin oligomers are not extracted from green tea

The Office Action alleges that the instantly claimed composition reads on the composition of Kuznicki *et al.* containing green tea extract and also proanthocyanidin oligomers having formula I and II because proanthocyanidin oligomers having formula I and II are extracted from green tea. Applicant respectfully disagrees.

As discussed above, the composition of Kuznicki *et al.* containing the green tea extract does not contain therapeutically effective amount of at least 70% pure proanthocyanidin selected as described in the instant claims. The Office Action has not provided any evidence to indicate that the proanthocyanidins of the instantly claimed compositions are present in the compositions containing green extract disclosed in Kuznicki *et al.* Therefore, the instant claims do not read on the composition of Kuznicki *et al.*

Teachings of Morimoto *et al.*

The Office Action appears to support the allegation of inherency based on the teachings of Morimoto *et al.* because the reference allegedly teaches proanthocyanidins or procyanidins wherein proanthocyanidins can be degraded to catechins and epicatechins.

Applicant respectfully submits that the instant claims are directed to pharmaceutical compositions containing therapeutically effective amount of at least 70% pure proanthocyanidin or a mixture of at least 70% pure proanthocyanidins selected as described in the instant claims. The claims are not directed to proanthocyanidins or procyanidins. Therefore, as further discussed below, the fact that Morimoto *et al.* describes the presence of several procyanidins, including compounds of formula I and II in 80% aqueous acetone extract of *Illicium anisatum* is not relevant to the instantly claimed compositions.

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Transition phrase "comprising"

The Office Action urges that the transitional phrase "comprising" does not exclude additional, unrecited elements or method steps. The Office Action concludes that the instant compositions read on the composition of Kuznicki *et al.* containing green tea extract. Applicant respectfully disagrees.

It is respectfully submitted that the instant claims are directed to compositions containing proanthocyanidins selected as described in the claims. The transitional phrase "comprising" allows for the presence of additional ingredients in the claimed compositions. Applicant respectfully submits that for a prior art reference to anticipate the claim, **the compositions disclosed in the reference must contain the proanthocyanidins described in the claims.** The fact that the transitional phrase "comprising" allows for the presence of additional ingredients in the claimed compositions is irrelevant to the question of anticipation. As discussed above, Kuznicki *et al.* does not disclose, inherently or literally, the presence of proanthocyanidins, as instantly claimed, in the compositions containing green tea extract disclosed therein. Therefore, the cited reference does not anticipate the instant claims.

Burden shifted to applicant

The Office Action alleges that the burden is shifted to applicant to show that the prior art product does not inherently possess proanthocyanidins and/or procyanidins as claimed in the instant product. Applicant respectfully disagrees.

As discussed in detail above, applicant has previously provided several references that describe the components of green tea. None of those references report the presence of proanthocyanidins selected from a group of proanthocyanidins characterized by Formula I or Formula II, and proanthocyanidins characterized by oligomeric combinations of Formula I and Formula II in green tea. The Office Action has not provided any reference to contradict applicants assertions. The Office Action supports the allegation of inherency based on the disclosure of Hashimoto *et al.* Applicant respectfully submits that Hashimoto *et al.* does not disclose components of green tea. The reference discloses the components of oolong tea. Applicant requests that the Examiner provide a reference showing the presence of proanthocyanidins, as instantly claimed, in the green tea. It is improper to shift the burden to applicant to prove that the green tea does not contain the proanthocyanidins as claimed in the

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instant claims. Applicant has provided references that describe the components of green tea. None the references of record indicate the presence of proanthocyanidins, as described in the instant claims, in green tea. Therefore, the burden is on the Examiner to provide a reference that indicates otherwise.

**THE REJECTION OF CLAIMS 28, 31-41 and 55-56 UNDER 35 U.S.C. § 102(b)
OVER JP 10245342**

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. § 102(b) as being anticipated by JP 10245342 because the reference allegedly discloses a pharmaceutical composition for diminishing the toxicity in nerve cells caused by β -amyloid protein containing a catechin or two or more of catechin such as epigallocatechin gallate and epicatechin gallate prescribed in effective amounts for diminishing the toxicity of β -amyloid protein, and a pharmaceutical carrier. The Office Action alleges that the green tea composition disclosed in the cited reference inherently contains proanthocyanidins oligomers having formula I and II and/or procyanidins such as the dimers and trimers of catechin and epicatechin because catechins are allegedly known to encompass these compounds which are known to be isolated from green tea.

Applicant notes that claims 39 and 40 are cancelled herein. The rejection is respectfully traversed with respect to pending claims 28, 31-38, 41 and 55-56.

Disclosure of JP 10245342

JP 10245342 discloses that green tea extract contains polyphenols such as tea catechin and/or theaflavin. The reference describes that the composition containing tea catechins and/or theaflavin can be used for diminishing the toxicity in nerve cells caused by β -amyloid protein. The reference does not disclose, inherently or literally, a composition containing a therapeutically effective amount of at least 70% pure proanthocyanidin selected from a group of proanthocyanidins characterized by Formula I or Formula II, and proanthocyanidins characterized by oligomeric combinations of Formula I and Formula II, and pharmaceutically acceptable salts of the foregoing proanthocyanidins.

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**Differences between the claimed subject matter and the disclosure of JP
10245342**

Claims 28 and 31-41

The compositions disclosed in JP 10245342 do not contain proanthocyanidins selected as described in the instant claims. The reference clearly describes that the compositions contain tea catechin and/or theaflavin extracted from green tea. As discussed above, there are no references of record to indicate that green tea extract contains the compounds of formula I or II or the oligomeric combinations thereof. Therefore, the reference can not disclose, inherently or literally, a pharmaceutical composition containing a therapeutically effective amount of at least 70% pure proanthocyanidin as described in the claim and a pharmaceutically acceptable carrier, diluent, or excipient.

Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, JP 10245342 does not anticipate a composition containing at least 70% pure proanthocyanidins selected from a group of proanthocyanidins characterized by Formula I or Formula II, and proanthocyanidins characterized by oligomeric combinations of Formula I and Formula II, and pharmaceutically acceptable salts of the foregoing proanthocyanidins, as claimed in claim 28. Because claims 31-38 and 41 depend from claim 28, JP 10245342 does not anticipate any of the claims dependent on claim 28. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

Claim 55-56

As discussed above, the reference does not disclose proanthocyanidins selected from a group of proanthocyanidins characterized by Formula I or Formula II, and proanthocyanidins characterized by oligomeric combinations thereof, and pharmaceutically acceptable salts of the foregoing proanthocyanidins. Therefore, the reference can not disclose a mixture of at least 70% pure proanthocyanidin, nor can it disclose a composition containing a therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins, as claimed in claim 55.

Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, JP 10245342 does not anticipate the composition claimed in claim 55. Because claim 56 depends from claim 55, JP 10245342 does not anticipate claim 56. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

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**THE REJECTION OF CLAIMS 28, 31-41 and 55-56 UNDER 35 U.S.C. § 102(b)
OVER HASHIMOTO *ET AL.***

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hashimoto *et al.* because Hashimoto *et al.* allegedly discloses a composition containing or inherently containing a catechin or two or more of catechins such as epigallocatechin and/or procyanidins or proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts and a pharmaceutical carrier. The Office Action urges that the oolong tea composition in Hashimoto *et al.* inherently comprises the instant compounds because these compounds are known to be isolated from oolong tea.

Applicant notes that claims 39 and 40 are cancelled herein. The rejection is respectfully traversed with respect to pending claims 28, 31-38, 41 and 55-56.

Disclosure of Hashimoto *et al.*

As discussed above, Hashimoto *et al.* discloses that polyphenolic constituents in the 80% aqueous acetone extract of oolong tea include flavan-3-ol, dimeric flavan-3-ols and proanthocyanidins. The reference does not disclose a pharmaceutical composition that contains a therapeutically effective amount of proanthocyanidins as instantly claimed.

**Differences between the claimed subject matter and the disclosure of
Hashimoto *et al.***

Claim 28 and 31-38 and 41

Hashimoto *et al.* describes an oolong tea extract in 80% aqueous acetone containing polyphenolic constituents including proanthocyanidins. It does not describe a pharmaceutical composition containing a therapeutically effective amount of at least 70% pure proanthocyanidin selected as described in the instant claims. The reference also does not disclose a pharmaceutically acceptable carrier, diluent, or excipient, as required in the instantly claimed compositions. Nor does it disclose, inherently or literally, compositions containing a therapeutically effective amount of at least 70% pure proanthocyanidin. As well known in the art, 80% aqueous acetone is not a pharmaceutically acceptable carrier. Therefore, oolong tea extract in 80% aqueous acetone containing proanthocyanidins is not within the scope of the instantly claimed pharmaceutical composition.

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Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, Hashimoto *et al.* does not anticipate the composition containing therapeutically effective amount of at least 70% pure proanthocyanidin as claimed in claim 28. Because claims 31-38 and 41 depend from claim 28, Hashimoto *et al.* does not anticipate claims 31-38 and 41. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

Claim 55-56

Hashimoto *et al.* further does not disclose a pharmaceutical composition containing a therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins selected as described in claim 55. As discussed above, the reference describes oolong tea extract containing proanthocyanidins in 80% aqueous acetone.

Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, Hashimoto *et al.* does not anticipate a composition containing therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins as claimed in claim 55. Because claim 56 depends from claim 55, Hashimoto *et al.* does not anticipate claim 56. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

Rebuttal to Examiner's Arguments

The Office Action alleges that Hashimoto *et al.* discloses catechins extracted and isolated from teas or other plants. It is urged that the percentage purity therein is known to significantly exceed a proportion percentage of the catechin present in a plant.

Applicant respectfully submits that Hashimoto *et al.* describes that components of oolong tea extract in 80% aqueous acetone were isolated. The reference further discloses polyphenolic constituents in the 80% aqueous acetone extract of oolong tea include flavan-3-ol, dimeric flavan-3-ols and proanthocyanidins. The reference does not disclose a therapeutically effective amount of proanthocyanidins in a pharmaceutically acceptable carrier as instantly claimed.

THE REJECTION OF CLAIMS 28, 31-41 and 55-56 UNDER 35 U.S.C. §102(b), OVER MORIMOTO *ET AL.*

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. § 102(b) as being anticipated by Morimoto *et al.* because Morimoto *et al.* allegedly discloses a composition containing a catechin

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or two or more catechins such as epigallocatechin and dimers and procyanidins in effective amounts and in pharmaceutical carrier. The Office Action urges that the compounds identified by Morimoto *et al.* are allegedly the instant compounds of formula I and II.

Applicant notes that claims 39 and 40 are cancelled herein. The rejection is respectfully traversed with respect to pending claims 23, 31-38, 41 and 55-56.

Disclosure of Morimoto *et al.*

As discussed above.

Differences between the claimed subject matter and the disclosure of Morimoto *et al.*

Claim 28 and 31-38 and 41

Morimoto *et al.* describes that *Illicium anisatum* extract in 80% aqueous acetone contains several procyanidins, including compounds of formula I and II. It does not describe, inherently or literally, a pharmaceutical composition containing a therapeutically effective amount of at least 70% pure proanthocyanidin selected as described in the instant claims. The reference also does not disclose a pharmaceutically acceptable carrier, diluent, or excipient, as required in the instantly claimed compositions. Nor does it disclose, inherently or literally, compositions containing a therapeutically effective amount of at least 70% pure proanthocyanidin. Applicant respectfully submits that 80% aqueous acetone is not a pharmaceutically acceptable carrier. Therefore, the *Illicium anisatum* extract in 80% aqueous acetone containing procyanidins is not within the scope of the instantly claimed pharmaceutical composition.

Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, Morimoto *et al.* does not anticipate the composition containing therapeutically effective amount of at least 70% pure proanthocyanidin as claimed in claim 28. Because claims 31-38 and 41 depend from claim 28, Morimoto *et al.* does not anticipate claims 31-38 and 41. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

Claim 55-56

Morimoto *et al.* further does not disclose a pharmaceutical composition containing a therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins selected as

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described in claim 55. As discussed above, the reference describes extract of *Illicium anisatum* containing procyanidins in 80% aqueous acetone.

Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, Morimoto *et al.* does not anticipate a composition containing therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins as claimed in claim 55. Because claim 56 depends from claim 55, Morimoto *et al.* does not anticipate claim 56. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

In response to the allegation in the Office Action that the compounds identified by Morimoto *et al.* are the instant compounds of formula I and II, applicant respectfully submits that the instant claims are directed to a pharmaceutical composition containing a therapeutically effective amount of at least 70% pure proanthocyanidin selected as described in claims 28-38 and 41 and a pharmaceutical composition containing therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins as claimed in claim 55. The claims are not directed to compounds of formula I and II. Therefore, presence of the compounds of formula I and II in 80% aqueous acetone extract of *Illicium anisatum* does not anticipate the instantly claimed compositions.

**THE REJECTION OF CLAIMS 28, 31-41 and 55-56 UNDER 35 U.S.C. §102(b),
OVER HATANO *ET AL.***

Claims 28, 31-41 and 55-56 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hatano *et al.* because Hatano *et al.* allegedly discloses a composition for anti-HIV containing or inherently containing a catechin or two or more of catechins such as epigallocatechin and dimers of proanthocyanidins oligomers having the formula I and II herein and/or procyanidins such as the dimers and trimers of catechin and epicatechin in effective amounts and a pharmaceutical carrier. The Office Action urges that the compositions in the cited reference inherently contains the instant compounds because these compounds are known to be isolated from *Camellia japonica* plants.

Applicant notes that claims 39 and 40 are cancelled herein. The rejection is respectfully traversed with respect to pending claims 28, 31-38, 41 and 55-56.

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Disclosure of Hatano *et al.*

Hatano *et al.* discloses eight tannins isolated from the leaf of *Camellia japonica*. The reference further discloses that the tannins isolated include complex tannins consisting of monomeric hydrolysable tannin and epicatechin, dimeric hydrolysable tannins and complex tannins composed of a dimeric hydrolysable tannin and epicatechin. The reference further discloses that the tannins isolated showed anti-HIV activity.

Differences between the claims and the disclosure of Hatano *et al.*

Claims 28, 31-38 and 41

Hatano *et al.* does not describe, inherently or literally, a pharmaceutical composition containing a therapeutically effective amount of at least 70% pure proanthocyanidin selected as described in claim 28. Hatano *et al.* discloses that an extract from leaf of *Camellia japonica* contains complex tannins consisting of monomeric hydrolysable tannin and epicatechin, dimeric hydrolysable tannins and complex tannins composed of a dimeric hydrolysable tannin and epicatechin. The reference does not disclose, inherently or literally, that the extract contains proanthocyanidins of Formula I or Formula II, and oligomeric combinations thereof.

Further, the compositions claimed in the instant claims contain therapeutic amount of at least 70% pure proanthocyanidin selected from a group of proanthocyanidins characterized by Formula I or Formula II, and proanthocyanidins characterized by oligomeric combinations of Formula I and Formula II, and pharmaceutically acceptable salts of the foregoing proanthocyanidins, selected for efficacy in treating amyloid in a mammalian subject. Since the cited reference does not disclose proanthocyanidins of formula I or II and the oligomeric combinations thereof, it can not disclose compositions containing therapeutic amount of at least 70% pure proanthocyanidin as instantly claimed.

Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, Hatano *et al.* does not anticipate a composition containing therapeutically effective amount of at least 70% pure proanthocyanidin as claimed in claim 28. Because claims 31-38 and 41 depend from claim 28, Hatano *et al.* does not anticipate claims 31-38 and 41. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

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Claim 55-56

Hatano *et al.* further does not disclose a composition containing a therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins as claimed in claims 55 and 56. As discussed above, the reference discloses an extract from *Camellia japonica* containing tannins. The reference does not disclose that the extract contains therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins selected from a group of proanthocyanidins characterized by Formula I or Formula II, and proanthocyanidins characterized by oligomeric combinations thereof, and pharmaceutically acceptable salts of the foregoing proanthocyanidins.


Thus, the cited reference does not disclose, either literally or inherently, every element of the claimed composition. Therefore, Hatano *et al.* does not anticipate a composition containing therapeutically effective amount of a mixture of at least 70% pure proanthocyanidins as claimed in claim 55. Because claim 56 depends from claim 55, Hatano *et al.* does not anticipate claim 56. Applicant respectfully requests that the rejection be reconsidered and withdrawn.

In view of the amendments and remarks herein, reconsideration and allowance of the application are respectfully requested.

Applicant hereby petitions under 37 C.F.R. §1.136 for three (3) month extension of time. Please apply any charges or any credits, to Deposit Account 50-3013.

Respectfully submitted,

Date: 8/23/05


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